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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,661	05/26/2000	JEAN-PIERRE SACHETTO		6789

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EXAMINER	
GEORGE, KONATA M	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/508,661	SACHETTO ET AL.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,15,22,24-27,33,37-39,42,43 and 45-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *33,37 and 56* is/are allowed.

6)☒ Claim(s) *1-3,6,15,22,24-27,38,39,42,43 and 45-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3, 6, 15, 22, 24-27, 33, 37-39, 42, 43 and 45-56 are pending in this application.

Request for Continued Examination (RCE)

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 4, 2006 has been entered.

Action Summary

2. The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Day is being maintained for the reasons stated in the previous office action.

3. The rejection of claims 27 and 38 under 35 U.S.C. 102(e) as being anticipated by Sachetto is being maintained for the reasons stated in the previous office action.

4. The rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over Day is being maintained for the reasons stated in the previous office action.

5. The rejection of claim 39 under 35 U.S.C. 103(a) as being unpatentable over Sachetto is being maintained for the reasons stated in the previous office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Day (US 5,380,522).

Day discloses in column 4, lines 5-63 a method of treating or preventing irritable bowel syndrome by oral administering singly or in combination an anion-binding polymer and a hydrophilic polymer. The hydrophilic polymer as taught by the prior art can be xanthan gum. It is the position of the examiner that when the composition is administered singly, the hydrophilic polymer would the sole therapeutic agent. Column 4, line 64 through column 5, line 7 teach that the composition when prepared is in the form of a dry powder, which can be admixed with a fluid prior to ingestion. It is also the position of the examiner that the claimed disease states would be inherent as they are diseases that result for irritable bowel syndrome and thus be treated as a result of taking the composition.

Response to Arguments

7. Applicants argue that the prior art of Day fails to exemplify the use of xanthan gum and is silent with respect to HPMC. Also it is argued that there is no coating or method of providing a delayed release profile and the difference between irritable bowel

syndrome (IBS) and irritable bowel disorder (IBD). Claims 1 and 2 are directed towards a composition comprising a polysaccharide and a carrier or vehicle, which is described in the prior art of Day. The treatment of inflammatory bowel disease is an intended use for the composition and carries no patentable weight. With respect to the intended use in a claim for a composition, a statement of intended use is of little patentable weight unless it specifically alters one or more ingredients of said composition. *In re Madder et al.* 143 USPQ 248. With respect to Day being silent with respect to the use of HPMC, the examiner has not claimed that Day discloses the use of HPMC in the composition. With respect to the delayed release of the composition, applicant has not disclosed in claim 1, what make the composition have a delayed response.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 27 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Sachetto (US 5,972,310).

Sachetto discloses in example 27, column 11, a composition comprising as a therapeutic agent xanthan gum in at a concentration of 0.5% by weight and a pharmaceutically acceptable carrier or vehicle i.e. H_2O.

Response to Arguments

9. Applicant argues that Example 1 of Sachetto does not teach that the composition is useful in treating IBD. With respect to the intended use in a claim for a composition, a

statement of intended use is of little patentable weight unless it specifically alters one or more ingredients of said composition. *In re Madder et al.* 143 USPQ 248. It is the position of the examiner that Sachetto teaches the claimed invention. Claim 27 is directed towards an enema comprising about 0.4 to about 2% w/w of xanthan gum and a pharmaceutically acceptable carrier or vehicle. Sachetto teaches a composition for rectal or vaginal administration comprising water, a liquefied gas, a surfactant and a water-soluble polymer. The water-soluble polymer is xanthan gum or hydroxypropyl methylcellulose in a concentration of up to 5%.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Day (US 5,380,522).

Day discloses in column 4, lines 5-63 a method of treating or preventing irritable bowel syndrome by oral administering singly or in combination an anion-binding polymer and a hydrophilic polymer. The hydrophilic polymer as taught by the prior art can be xanthan gum. It is the position of the examiner that when the composition is administered singly, the hydrophilic polymer would be the sole therapeutic agent. Column 4, line 64 through column 5, line 7 teach that the composition when prepared is

in the form of a dry powder, which can be admixed with a fluid prior to ingestion. The prior art does not teach composition containing concentrations of the polysaccharide from about 400 to about 2000 mg.

With respect to the claimed concentration, absent a clear showing of criticality, the determination of a particular concentration is within the skill of the ordinary worker as part of the process of normal optimization to achieve the desired results of treating inflammatory bowel disease.

Response to Arguments

11. See above for response to arguments.

12. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sachetto (US 5,972,310).

Sachetto discloses in example 27, column 11, a composition comprising as a therapeutic agent xanthan gum in at a concentration of 0.5% by weight and a pharmaceutically acceptable carrier or vehicle i.e. H_2O. The prior art does not teach composition containing concentrations of the polysaccharide from about 400 to about 2000 mg.

With respect to the claimed concentration, absent a clear showing of criticality, the determination of a particular concentration is within the skill of the ordinary worker as part of the process of normal optimization to achieve the desired results of treating inflammatory bowel disease.

Response to Arguments

13. See above for response to arguments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-3, 6, 15, 22, 24-26, 42, 43 and 45-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant recites "an amount effective" to treat IBD in the claims. It is indefinite to how much is "an amount effective" to IBD i.e. 1%, 10%, 1mg, 10mg, etc. Please amend the claims to recite a specific amount.

Allowable Subject Matter

15. Claims 33, 37 and 56 are allowed. The prior art does not teach a liquid enema comprising hydroxypropylmethylcellulose as the sole therapeutic active agent in a concentration from about 1 to 20%, together with a pharmaceutically acceptable carrier or vehicle.

Conclusion

16. Claims 1-3, 6, 15, 22, 24-27, 38, 39, 42, 43 and 45-55 are rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

12/11/06